APPENDIX - E
BLOOD BANK USER MANUAL
CHANGE CONTROL PROCEDURE

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VA Medical Center	**SUBJ: Change Control for Blood Bank Files**		
Street Address	System: Information Management		
City, State, Zip Code	Prepared by:		
	Approved by:		
	Date Implemented:		
	Supersedes:		

Change Control for Blood Bank Files

Purpose

To provide a mechanism for controlling changes made to files which have control over the functionality of the blood bank software. This includes:

- FUNCTION FIELD file (#61.3)
- BLOOD BANK UTILITY file (#65.4)
- BLOOD PRODUCT file (#66)
- LABORATORY SITE file (#69.9)

Once the initial system validation is performed and the software has been implemented in production, file changes may be necessary for a variety of reasons. Some of these include:

- DHCP software patch/new versions
- Change in standard operating pro cedure
- Addition of new blood products to BLOOD PRODUCT file (#66)
- Addition of new supplier to an existing blood product in BLOOD PRODUCT file (#66)
- Change in characteristic/property for supplier information for blood product in BLOOD PRODUCT file (#66), e.g. cost
- Change in donor history questions in BLOOD BANK UTILITY file (#65.4)

In order to ensure appropriate process control for file changes, a series of request forms are provided. At the end of each form is an area entitled Change Control Summary which should be used for documentation.

For each file, a table is also included which details the validation requirements for file changes.

Policies

1. In general, file changes are requested and made by the Blood Bank supervisory staff who have the required security access; however, if specific changes are needed for fields which do not have software control, these changes can be made by the Laboratory Information Manager if necessary. For example, units of blood/blood components might be received from a supplier not previously entered for that particular component. Since the units cannot be logged in until this is resolved, the changes should be made and documented using the designated form. A few changes require a higher level of security and file access. These are specifically noted on the request forms.

2. Editing of the blood bank files should always be done using the appropriate blood bank options, unless otherwise designated. These options are locked with a specific key to provide an additional level of security. Access to these options is controlled both by Kernel security, which requires the appropriate security key, and by menu management which controls access to the menu options.

3. Impact analysis is part of documenting the change control process. This involves studying/assessing the system to determine the impact of the change. This might include effects on related functionality or system output. The information provided in the tables for each file indicates the purpose of the field and options/functionality which are affected by that specific field. Additional details are also provided is the Blood Bank User Manual for the specific option referenced. According to the AABB guidelines, "Changes may not be made until the impact or risk to the system has been evaluated, a controlled process has been executed, the results have been obtained and analyzed, and the output has been found acceptable." This analysis can be documented on the series of forms provided entitled "Requests for File Changes.." Areas have been provided on these forms to assess and document training, procedure revisions and validation outcomes.

4. Validation is required when changes are made in the files which perform some type of software control function. Once the system validation has been completed, each change made to the file needs to be evaluated to determine whether the change requires validation. This should be done on a field by field basis using the tables of validation requirements included on for each file.

a. In some cases, the changes are cosmetic and are only being made to fields which involve a characteristic/property change. In these cases, the change must be documented; however, the extent of validation can be limited to an assessment of whether the change is reflected in the software function. For example, the addition of a new supplier to the BLOOD PRODUCT FILE (#66) only requires that the supplier be available as a choice in the "Log-in regular (invoices) [LRBLILR]" option.
This can be documented using the forms included in this procedure which include the date the change was made, the person making the change and the fact that the test case yielded acceptable results.

b. In other cases, the change will involve a field which performs some type of software control. In these case, it is necessary to perform sufficient validation to be able to conclude that the product to which the change is being is substantially equivalent to one which has already undergone validation. For example, if a decision has been made to no longer allow a specific blood product to be requested because of a policy change **and** another blood product already exists in the BLOOD PRODUCT file (#66) which has the CAN BE REQUESTED field set to NO **and** this has already been validated, the extent of validation for the change can be limited to an assessment of whether the change is reflected in the software function. For example, that particular product should no longer be accessible using the "Blood component requests [LRBLPCS]" option in the Patient [LRBLP] menu. This can be documented using the forms included in this procedure which

include the date the change was made, the person making the change and the fact that the test case yielded acceptable results.

c. When new products are added to the file, it is necessary to document that the new entry functions as intended. Validation cases need to be developed which include the areas which require validation when changes are made.

d. For tracking purposes, th e results of validation performed for file changes should be entered into the BLOOD BANK VALIDATION file (#66.2) using the Blood Bank Software Validation Documentation [LRBLVAL] option in the Supervisor [LRBLS] menu.

5. Communication of the change will vary based on the impact analysis. In some cases, training will be required, as will revisions in standard operating procedures (SOP). In other cases, training and/or SOP changes will not be necessary; however, the personnel who may be performing a particular task may need to be informed of the change and an electronic mail message may be adequate. In still other cases, such as the addition of a new supplier to an existing blood product, communication is probably unnecessary as the software either accepts or rejects the choice and on-line help allows display of all available choices.

6. Printouts of the files should be requested once the changes have been made to ensure that the entries are accurate and that all changes have been adequately documented. The Laboratory Information Manager can generate these printouts upon request.

7. At a minimum, the change control records should include:

   a. a description of the change,
   b. the date of the change,
   c. the person making the change,
   d. equipment or other functions that are affected by the change,
   e. an authorization signature,
   f. the validation risk assessment, and
   g. the documentation of approval and assistance.

Procedure

A. Planning

1. DHCP Patch/Version Update

a. Review the information provided with the patch/new version to determine the scope of the changes.

b. Determine the potential impact of this specific change on your individual division/ facility.

c. Determine what the training needs are, i.e., who will require training and what type of training is necessary.

d. Have the patch/new version loaded in a test account so that the functionality and the impact of the patch can be assessed.

e. Coordinate the training needs, the validation and the implementation of the patch/new version so that it has the least amount of impact on normal operations of the facility.

2. Addition of new products to the BLOOD PRODUCT file (#66)

a. Complete the form entitled “Request for File Changes to the BLOOD PRODUCT file (#66)”. Indicate the information to be entered for each field.

b. Make the necessary changes in th e procedure manual and any other places that listings of the products are detailed.

3. Changes to existing entries in BLOOD PRODUCT file (#66)

Examples:

- addition of new supplier to existing blood product
- change in the cost in the supplier information for a blood product

a. Complete the form entitled “Request for File Changes to the BLOOD PRODUCT file (#66)”. Indicate the information to be entered for each field.

4. Changes to existing entries in FUNCTION FIELD file (#61.3)

Examples:

- Change in the clinical significance of antibody, i.e. requiring units to be typed and antigen negative for corresponding antigen
- Change in wording of the information on the Blood Bank Consultation Report
- Addition of new journal reference to the Blood Bank Consultation Report

a. Complete the form entitled "Request for File Changes to th e FUNCTION FIELD file (#61.3)". Indicate the information to be added or changed for each field.

5. Changes to existing entries in BLOOD BANK UTILITY file (# 65.4)

Examples:

- Change in donor reaction code
- Change in donor history questions
- Change in the wording of the donor consent

a. If the changes do not involve donor history questions or the blood donor consent, complete the form entitled "Request for File Changes to the BLOOD BANK UTILITY file (#65.4)". Indicate the information to be entered for each field.

b. If the change involves donor history questions, complete the form entitled "Request for File Changes to the BLOOD BANK UTILITY file (#65.4)-DONOR HISTORY ESTIONS." Indicate the information to be entered/changed.

c. If the change involves the donor consent, complete the form entitled "Request for File Changes to the BLOOD BANK UTILITY file (#65.4)-DONOR CONSENT." Indicate the information to be entered/changed.

6. Changes to existing entries in LABORATORY SITE file (#69.9)

Examples:

- Exclusion of the fields for direct antiglobulin testing in the LRBLSCREEN template used to enter Type and screen test results
- Elimination of the requirement to include ALT testing on blood donors

a. Complete the form entitled "Request for File Changes to the LABORATORY SITE file (#69.9)". Indicate the information to be added or changed for each field.

B. Training

Training can be accomplished in a variety of manners and should be tailored to the scope and application of the file change. In some cases, the change may be transparent to the user and no training may be required. In other cases, the change may be transparent to the user, but may involve changes in control functions of which the user needs to be cognizant and communication of the change via a mail message may be sufficient. In still other cases, the user may encounter changes in functionality for which hands-on training might be appropriate in conjunction with some type of competency assessment.

1. DHCP Patch/Version Update

Training needs will vary based on the scope of the patch and will need to be determined on a patch by patch basis.

2. Addition of new products to the BLOOD PRODUCT file (#66)

No specific computer training is necessary for additions to the BLOOD PRODUCT file (#66) unless:

a. there are changes in processes or in standard operating procedures which might be associated with these file changes may require training, or

b. the entries for the new product involve software control for which training has not previously been provided.

3. Changes to existing entries in BLOOD PRODUCT file (#66)

a. No specific computer training is necessary for additions of new suppliers to an existing blood product in File (#66).

b. Change in fields which do not involve software control require no specific computer training. For example, changes in the cost subfield for supplier information represents a characteristic/property which does not require training.

4. Changes to existing entries in BLOOD BANK UTILITY file (#65.4)

No specific computer training is necessary for additions to the BLOOD BANK UTILITY file (#65.4) unless:

a. there are changes in processes or in standard operating procedures which might be associated with these file changes may require training, such as changes in donor history questions, or

b. the entries for the new entry involve software control for which training has not previously been provided.

5. Changes to existing entries in FUNCTION FIELD file (#61.3)

No specific computer training is necessary for additions to an existing BLOOD GROUP ANTIGEN or BLOOD GROUP ANTIBODY in File 61.3.

6. Changes to existing entries in the LABORATORY SITE file (#69.9)

Specific computer training is probably necessary for the majority of changes in this file, if not all, will also involve a change in standard operating procedures.

C. Implementation

1. DHCP Patch/Version Update

Proceed as indicated in the information provided with the patch when it is released. In some cases which involve complex patches, extended documentation will be provided in the form of Release Notes and Implementation Guide.

2. Addition/Changes to the BLOOD PRODUCT file (#66)

a. Use the Edit blood products file [LRBLSEB] option in the Edit blood bank files [LRBLEF] submenu of the Supervisor [LRBLS] menu.

b. Once the changes have been completed, request a full printout of the BLOOD PRODUCT file (#66) to ensure that the entries are accurate and that all changes have been adequately documented.

c. Communicate the changes to all personnel directly or indirectly affected by the change IF the change involves knowledge needed to perform their assigned duties. If training is not required, but information needs to be disseminated, use of electronic mail is the method of choice whenever possible as this provides a built-in tracking mechanism to document whether the recipient has received/read the information.

3. Changes to existing entries in BLOOD BANK UTILITY file (#65.4)

a. Use the Edit blood bank utility [LRBLSEU] option in the Edit blood bank files [LRBLEF] submenu of the Supervisor [LRBLS] menu.

b. If editing is limited to changes in field 2 DONOR HISTO RY, use the Edit donor history questions [LRBLSEH] option in the Blood donor edit options [LRBLSD] submenu of the Supervisor [LRBLS] menu.

c. If editing is limited to changes in field 3 COMMENT which controls the wording of the donor consent which appears at the end of the donor history, consent and physical form, use the Edit donor consent[LRBLDCX] option in the Blood donor edit options..[LRBLSD] submenu of the Supervisor [LRBLS] menu.

d. Once the changes have been completed, request a full prin tout of the BLOOD BANK UTILITY File (#65.4) to ensure that the entries are accurate and that all changes have been adequately documented.

e. Communicate the changes to all personnel directly or indirectly affected by the change IF the change involves knowledge needed to perform their assigned duties. If training is not required, but information needs to be disseminated, use of electronic mail is the method of choice whenever possible as this provides a built-in tracking mechanism to document whether the recipient has received/read the information.

4. Changes to existing entries in FUNCTION FIELD file (#61.3)

NOTE: This file is also used for anatomic pathology and microbiology. This procedure applies only to limited specific fields are applicable as shown in the table.

a. Use the Edit Corresponding Antigen/Antibody [LRBLSNO]option in the Supervisor menu [LRBLS]. This option will limit access to only those specific fields which can be edited without a higher level of security.

b. Do NOT request a full printout of the FUNCTION FIELD file (#61.3) in an attempt to ensure that the entries are accurate and that all changes have been adequately documented. This file includes many entries other than those designated as BLOOD GROUP ANTIGEN or BLOOD GROUP ANTIBODY. Instead, requesting a printout based on a search where the IDENTIFIER = BLOOD GROUP ANTIGEN or IDENTIFIER = BLOOD GROUP ANTIBODY in combination with the print template LRBL ANTIBODY LISTING will provide a report which includes the relevant fields.

5. Changes to LABORATORY SITE file (#69.9)

NOTE: Only one entry exists in this file, i.e. HOSPITAL. Additions to the file cannot be made.

This file is also used by the main laboratory package and by other packages such as OERR. This procedure applies only to limited specific fields applicable to the Blood Bank module as shown in the table.

a. Use the Edit blood bank site parameters [LRBLSSP] option in the Edit blood bank files [LRBLEF] submenu of the Supervisor [LRBLS] menu. This option restricts access to only specific fields applicable to the Blood Bank software.

b. If the change involves a change to multidivisional functionality, the change requires a higher level of security access and **cannot** be made using the Edit blood bank site parameters [LRBLSSP] option in the Edit blood bank files [LRBLEF] submenu of the Supervisor [LRBLS] menu. This change must be done by either the Laboratory Information Manager or IRM staff who have a higher level of security access, as indicated on the form for requesting changes and in the table of validation requirements for this file.

c. Once the changes have been completed, request a full printout of the LABORATORY SITE file (#69.9) to ensure that the entries for the edited fields are accurate and that all changes have been adequately documented.

D. Validation Requirements

Consult Appendix D for details on the performance of validation testing, development of a Validation Plan, evaluation of the testing and procedures to follow in the event that the software does not perform as expected. Detailed information for these areas is **NOT** included in this procedure.

1. DHCP Patch/Version Update

In the majority of cases, patches are released with detailed descriptions and test scenarios; however, a revised listing of the control functions and a revised set of test case tracking

worksheets are NOT provided. These are only provided for version updates and patches which involve extensive changes to multiple files, options or functionality.

The extent of the Validation Plan would depend on the scope of the validation to be performed. For example, the plan for a version update or a patch involving extensive routine and/or data dictionary changes would be significantly different than that for a patch involving a single option and 1-2 routines.

2. Additions/Changes to Files unrelated to patches/version updates

a. For each file, a table has been included which provides details about the specific fields for the file. This table includes:

(1) Field number and name

(2) Type of data, e.g., free text, number, set

(3) Purpose of the field, e.g., software control function, characteristic/ property, algorithm function

(4) Validation requirements if change is made

(a) Not applicable - used primarily for fields that are not currently in use or that involve some characteristic/property that does not involve the safety, purity or potency of a unit of blood/blood component

(b) Not needed - used to indicate that no additional validation is necessary once it has been demonstrated that other comparable file entries have been validated and found to be acceptable. For example, the field entries for AS-1 Red Blood Cells and CPDA-1 Red Blood Cells would probably be nearly identical and each would not need to be separately validated for those which were identical.

(c) Required - used to indicate that validation is required. Brief additional information is provided to indicate which option should be used to validate the functionality. Further details should be obtained from the Blood Bank User Manual documentation for that specific option and from previous validation test cases involving that specific option.

b. If the various forms entitled "Request for File Changes to the ..." are used, no elaborate validation plan is needed as this form provides for the necessary documentation.

(1) Training needs, including dates of completion and comments if appropriate

(2) Procedure needs, including the name of the standard operating procedure and the date the change was made if appropriate

(3) Validation testing summary, including the risk assessment (validation needed or not needed), the date and person performing the testing if it was needed, whether the results were acceptable and comments if appropriate

(4) Supervisory review summary, including the person(s) authorizing the change

E. Change Control Summary

1. As indicated in the information on validation testing which is included in Appendix A & Appendix D of the Blood Bank User Manual, specific procedures must be followed if a problem is identified in which the software does not function as intended or as detailed in the documentation. See the flowchart on page E-14 for an overview of support process for the Blood Bank software. In general, the problem/error should first be reported to the Laboratory Information Manager, followed by the IRM staff at the facility, then to a member of the CLIN2 support team. Reporting to the CLIN2 team can be done either by telephone or by initiating a NOIS call.

a. If a problem is identified and the nature of the problem indicates that there is a system deficiency which can be handled by an alteration in the workflow processes until the situation is corrected, the Blood Bank Supervisor may decide to continue implementation of the change, provided the alternative procedures are implemented and the problem is reported.

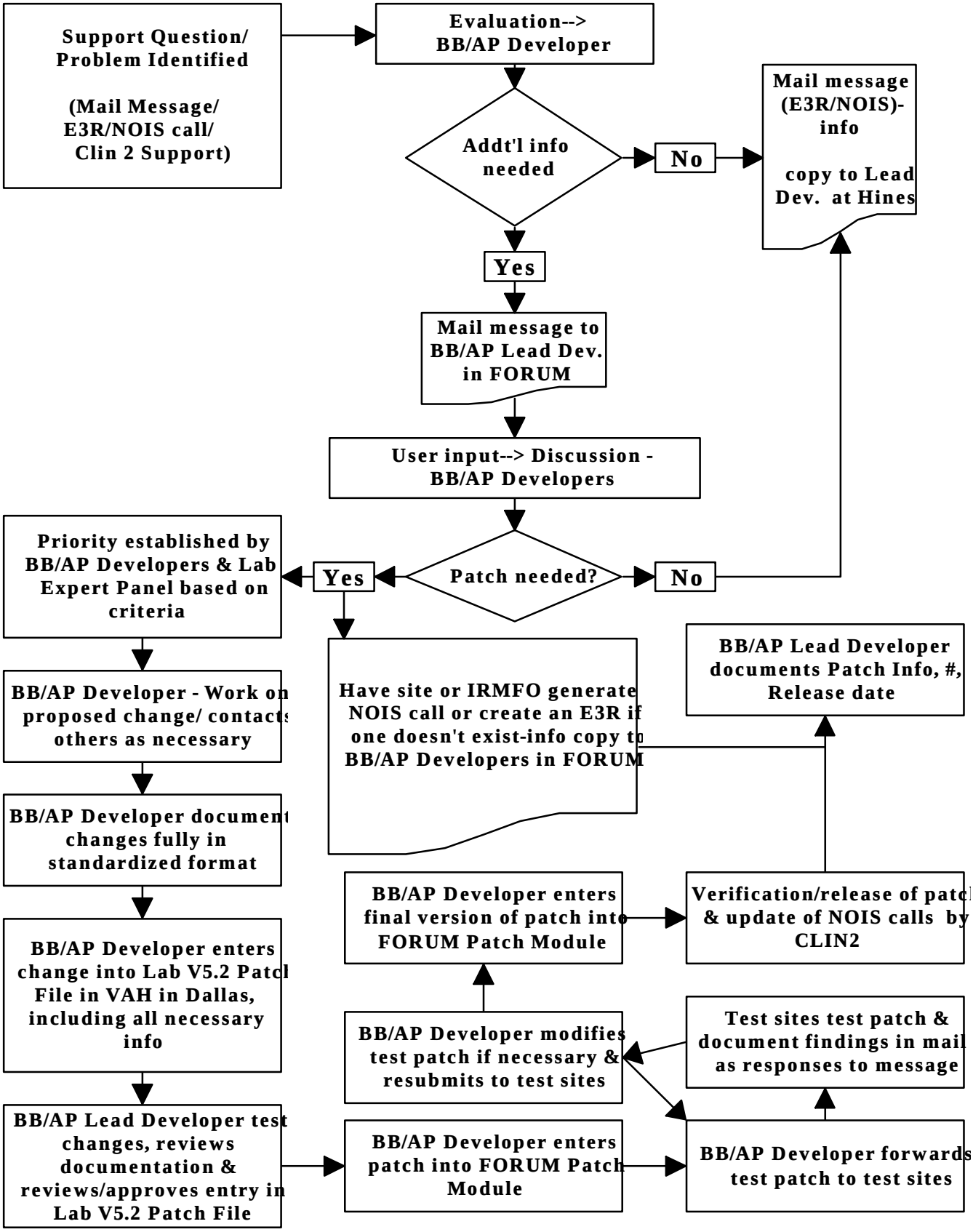
b. If the nature of the problem indicates that there is a system deficiency which cannot be handled by an alteration in the workflow processes, the Blood Bank Supervisor should NOT continue with implementation of the change until the problem is satisfactorily resolved.

2. Make sure that the change control records include at least:

a. a description of the change,
b. the date of the change,
c. the name of the person making the change,
d. any equipment or other functions that are affected by the change,
e. an authorization signature,
f. a validation risk assessment, and
g. documentation of approval and acceptance.

If the forms provided in this appendix are utilized, an area is provided at the end of each request form to document this information.

Process Flow for Laboratory Version 5.2 Blood Bank and Anatomic Pathology Support


Support Question/ Problem Identified
(Mail Message/ E3R/NOIS call/ Clin 2 Support)
Evaluation--> BB/AP Developer
Addt'l info needed
No
Mail message (E3R/NOIS)- info
copy to Lead Dev. at Hines
Yes
Mail message to BB/AP Lead Dev. in FORUM
User input--> Discussion - BB/AP Developers
Patch needed?
Yes
No
Priority established by BB/AP Developers & Lab Expert Panel based on criteria
Have site or IRMFO generate NOIS call or create an E3R if one doesn't exist-info copy to BB/AP Developers in FORUM
BB/AP Lead Developer documents Patch Info, #, Release date
BB/AP Developer - Work on proposed change/ contacts others as necessary
BB/AP Developer document changes fully in standardized format
BB/AP Developer enters change into Lab V5.2 Patch File in VAH in Dallas, including all necessary info
BB/AP Developer enters final version of patch into FORUM Patch Module
Verification/release of patch & update of NOIS calls by CLIN2
BB/AP Developer modifies test patch if necessary & resubmits to test sites
Test sites test patch & document findings in mail as responses to message
BB/AP Lead Developer test changes, reviews documentation & reviews/approves entry in Lab V5.2 Patch File
BB/AP Developer enters patch into FORUM Patch Module
BB/AP Developer forwards test patch to test sites

Forms for Requesting File Changes and Validation Requirements for File Changes

Request for File Changes to the BLOOD PRODUCT file

TYPE OF REQUEST:
- ❒ Additional (new) blood product
- ❒ Change in blood product entry
  (Specify: _____)

REASON FOR REQUEST: ❒ DHCP Software Patch (Patch #: _____)
- ❒ Change in standard operating procedure
- ❒ Change in scope of services provided
- ❒ Other (Specify: _____)

NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. Editing of the file entries can be done using the Edit blood products file [LRBLSEB] option in the "Edit blood bank files [LRBLEF] submenu of the Supervisor [LRBLS] menu.

Consult the table detailing Validation Requirements for File Changes for the BLOOD PRODUCT file (#66) which includes the columns labeled “purpose of the field” and “changes require validation?” for the rationale and details regarding the functionality of the field and whether additions/changes require software validation.

Additions/Change to the BLOOD PRODUCT File (#66)

Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.01 NAME identifies product		(free text, 2-40 characters)	Accept. Unaccept.
.02 ABBREVIATION characteristic used to access/identify this specific component		(free text, 1-4 characters)	Accept. Unaccept.
.03 CAN BE MODIFIED determines whether this product can be modified into other products		(set) YES NO	Not needed Accept. Unaccept.
.04 IDENTIFIER determines whether this file entry can be accessed (only component/derivatives with IDENTIFIER = BB should be accessible at any prompt which references component		(set) BB AB T	Not needed Accept. Unaccept.
.05 PRODUCT CODE characteristic used to by bar code reader or by manual entry to access this specific component		(free text, 1-5 characters)	Not needed Accept. Unaccept.

.055 DOD CODE used by the Department of Defense		(free text, 2-5 characters) NA for VA use	Not needed Accept. Unaccept.

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.06 MODIFICATION CRITERIA determines the edit template used when this product is selected during modification of another product		(set) DIVIDED POOLED WASHED/ FROZEN LEUKOCYTE POOR REJUVENATED DEGLYCEROLIZED IRRADIATED SEPARATED	Accept. Unaccept.
.07 PATIENT/PRODUCT ABO determines whether units selected for a patient must be identical or must be red cell compatible		(set) MUST MATCH MUST BE COMPATIBLE	Not needed Accept. Unaccept.
.08 PATIENT/PRODUCT RH determines whether units selected for a patient must be identical or must be red cell compatible		(set) MUST MATCH MUST BE COMPATIBLE	Not needed Accept. Unaccept.
.09 PATIENT/PRODUCT REQUIREMENT determines whether units must be crossmatched or if the product contains large volumes of plasma which should be compatible with the patient's red cells		(set) CROSSMATCH PLASMA/ PATIENT COMPATIBILITY	Not needed Accept. Unaccept.
.1 VOLUME (ml) characteristic		(number, 0 decimals, 1-1000)	Not needed
.11 DAYS LEFT calculates the new expiration date required if this product is prepared from another product present in inventory		(number, 2 decimals, .16-2557)	Accept. Unaccept.
.12 ANTICOAGULANT/ ADDITIVE prevents mixing of components during modifications (e.g., a product which has CPDA-1 cannot be modified to a product which has CPD as the anticoagulant)		(set) CPD ACD CPDA-1 ADSOL	Not needed Accept. Unaccept.
.13 COLLECTION/PREP HOURS in the donor module options only, i.e., indicates the maximum time allowable between the DATE/TIME COLLECTION STARTED (65.54,4.2) and the DATE/TIME STORED (65.66,.03)		(number, 0 decimals, 1-144)	Accept. Unaccept.

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.135 MAXIMUM STORAGE DAYS in the donor module option, calculates the default shown for the EXPIRATION DATE (65.66,.04); in the inventory module option, screens the entry for the EXPIRATION DATE/TIME (65,.06) for potential data entry errors		number, .16-3652 (4 hr to 10 years)	Accept. Unaccept.
.14 MODIFIED BEFORE RELEASE prevents issue/relocation of products which must be modified such as Frozen Red Blood Cells which must be deglycerolized before issue		(set) YES NO	Accept. Unaccept.
.15 CAN BE REQUESTED prevents selection of products which should not be accessed/selected		(set) YES NO	Not needed Accept. Unaccept.
.16 PATIENT SPECIMEN AGE ALLOWED prevents selection of units of this product for specimens IF the difference between the current time and the BLOOD SAMPLE DATE/TIME exceeds the entry in this field for this product		number in hours, 24-240 (1 to 10 days)	Not needed Accept. Unaccept.
.18 RETYPE AFTER PREPARATION determines whether units of this product must be retyped before issue/release. If YES, units which are created using the [LRBLIDN] option will appear on the Inventory testing worksheet generated by [LRBLIW].		(set) YES NO	Not needed Accept. Unaccept.

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.19 CONTAINS RED BLOOD CELLS (1) determines whether units of this product must be retyped before issue/release. If YES, units will not be able to be released using [LRBLIDR] until required recheck results are entered. (2) used for sorting purposes on some reports		(set) YES NO	Not needed Accept. Unaccept.
.21 MAX AGE FOR PEDIATRIC USE determines whether units of this product can be modified into pediatric units		(number in days, 0 decimals, 1-1827)	Accept. Unaccept.
.22 PEDIATRIC PRODUCT determines which products can be accessed when modifying a unit in inventory using the [LRBLPED] option; (both must also have same entry in the ANTICOAGULANT/ ADDITIVE field)		pointer to another entry in File 66	Accept. Unaccept.
.23 SPECIFIC GRAVITY in the [LRBLPED] option, i.e., used to convert the volume of the unit in mls. into an equivalent wt. in gms.		(set) 1.06 (whole blood) 1.08 (red cells) 1.03 (plasma)	Not needed Accept. Unaccept.
.24 MAXIMUM INFUSION TIME(MIN) used to determine which units should be included in the Prolonged transfusion times report generated by the [LRBLPIT] option		number, 0 decimals, 1-999 (minutes)	Not needed Accept. Unaccept.
.25 AUTOLOGOUS/ DIRECTED COMPONENT determines whether additional data is needed to restrict selection of the unit for the intended patient (RESTRICTED FOR field)		(set) AUTOLOGOUS DIRECTED NEITHER	Not needed Accept. Unaccept.

.26 ADMINISTRATIVE CATEGORY used to determine which units should be included in several different reports, e.g. Phenotyped units available [LRBLIPH] and Blood Bank Administrative Data [LRBLA]		(set) WHOLE BLOOD RBC FROZEN RBC DEGLYC RBC LEUCODEPLETED RBC WASHED RBC FFP	Not needed Accept. Unaccept.

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.27 POOLED PRODUCT determines whether a unit of that specific product can be accessed thorough the Edit pooled blood product [LRBLJM] option; used by the integrity check routine in the [LRBLII] option to determine which fields may have missing data		(set) YES NO	Not needed Accept. Unaccept.
.28 ASK BAG LOT # determines whether the BAG LOT # field (65,1.1) should be included in the edit template used by the [LRBLIDN] option when modifying units		(set) YES NO	Accept. Unaccept.
1 DESCRIPTION (Subfile 66.09) .01 DESCRIPTION intended for use for display purposes in future		(word processing; 1-50 characters)	Not applicable
2 SYNONYM (Subfile 66.021) .01 SYNONYM used for look-up access purposes only		(free text; 2-50 characters)	Accept. Unaccept.
3 MODIFY TO (Subfile 66.03) .01 MODIFY TO determines which products can be accessed when modifying a unit in inventory using the [LRBLIDN] option		(pointer to File 66-enter name)	Accept. Unaccept.
3 MODIFY TO (Subfile 66.03) .02 NOT ONLY ONE ALLOWED determines whether more than one product may be created when modifying a unit in inventory using the [LRBLIDN] option		(set) YES NO	Accept. Unaccept.
4 SUPPLIER (Subfile 66.01) .01 SUPPLIER name of supplier - determines characteristics based on subfields detailed below		(free text; 1-30 characters)	Accept. Unaccept.

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
4 SUPPLIER (Subfile 66.01) used for look-up and information purposes only .03 ADDRESS LINE 1 .04 ADDRESS LINE 2 .05 ADDRESS LINE 3 .06 CITY .07 STATE .08 ZIP CODE .09 PHONE		.03 ADDRESS LINE 1 (free text; 1-30 charac.) .04 ADDRESS LINE 2 (free text; 1-30 charac.) .05 ADDRESS LINE 3 (free text; 1-30 charac.) .06 CITY (free text; 1-30 charac.) .07 STATE (pointer to State File(#5)) .08 ZIP CODE (free text; 5-9 characters) .09 PHONE (free text; 4-30 charac.)	Accept. Unaccept.
4 SUPPLIER (Subfile 66.01) .02 COST calculates expenses for reports		(number, 0-9999)	Accept. Unaccept.
4 SUPPLIER (Subfile 66.01) .1 SUPPLIER PREFIX NUMBER determines the prefix to be added to the unit ID scanned by the bar code reader when entering a unit in inventory in the [LRBLILR] option		(free text, 1-3 characters)	Accept. Unaccept.
4 SUPPLIER (Subfile 66.01) .11 REGISTRATION NUMBER used for reference/information only		(free text, 7-9 digits)	Not applicable

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
4 SUPPLIER (Subfile 66.01) .12 UNIT LABEL NON-STANDARD controls the translation of the unit ID scanned by the bar code reader when entering a unit in inventory using the [LRBLILR] option		(set) YES Non-Standard= numeric NO Standard=alphanumeric	Accept. Unaccept.
1 LOT # (Subfile 66.02) .01 LOT # .02 EXPIRATION DATE not currently used by the software		not currently used by the software	Not applicable
5 CRITERIA FOR USE (Subfile 66.05) .01 CRITERIA FOR USE intended for use for display purposes in future		(word processing)	Not applicable
6 TESTS TO CHECK (Subfile 66.08) used to identify/flag non pre-op component requests which exceed the audit criteria (may enter more than one) .01 TESTS TO CHECK .02 SPECIMEN .03 > OR < TEST VALUE		.01 TESTS TO CHECK pointer to Laboratory Test File (#60) .02 SPECIMEN pointer to Topography Field File (#61) .03 > OR < TEST VALUE free text	Accept. Unaccept.
7 REQUISITION INSTRUCTIONS (Subfile 66.07) .01 REQUISITION INSTRUCTIONS intended for use for display purposes in future		(word processing) Not applicable	Not applicable

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
8 PRE-OP TESTS TO CHECK (Subfile 66.08) used to identify/flag non pre-op component requests which exceed the audit criteria (may enter more than one) .01 PRE-OP TESTS TO CHECK .02 SPECIMEN .03 > OR < TEST VALUE		.01 TESTS TO CHECK pointer to Laboratory Test File (#60) .02 SPECIMEN pointer to Topography Field File (#61) .03 > OR < TEST VALUE free text	Accept. Unaccept.
10 ASSOCIATED DIVISION (Subfile 66.1) .01 ASSOCIATED DIVISION limits access to products based the division of the user at a given point in time with the products attempting to be requested; allows multiple entries for multidivisional facility		(pointer to INSTITUTION File (#4))	Not needed Accept. Unaccept.
500 WKLD CODE (Subfile 66.06) .01 WKLD CODE used for workload capture by the [LRBLIDN] option and the [LRBLDCP] option		(pointer to WKLD CODE File (#64)) 86183 Irradiation 86269 Cryo prep (≥4) 86271 Cryo prep 86272 Cryo thaw/pooling 86275 Frozen Bld Prep 86276 Deglyc. Froz. Bld 86277 Rejuvenation 86390 Plt prep (≥4) 86392 Plt prep 86393 Platelet pooling 86670 Washed RBC 86795 RBC prep 86796 RBC prep (≥4) 86800 FFP 86801 FFP prep (≥4) 86805 FFP thawing 86810 Divided/separated	Not needed Accept. Unaccept.

Change Control Summary for Additions/Changes to the BLOOD PRODUCT file (#66)

Training

❒ None needed ❒ Completed/documented (Date _____ by _____)

Comments: _____

Documentation

❒ New printout of file obtained

❒ No procedure change needed ❒ Procedure change completed (Date _____)

Name of procedure: _____

Validation Risk Assessment and Testing Summary:
*see separate attached documentation for test cases

Date Tested _____ Tested by: _____

❒ None needed ❒ Acceptable* ❒ Unacceptable*

Comments: _____

Supervisory Review:

Signature: _____ (BB Supervisor)

Signature: _____ (BB Medical Director)

Signature: _____ (LIM/IRM Staff)

Date Implemented in Production: _____

Validation Requirements for File Changes to BLOOD PRODUCT file (#66)

BLOOD PRODUCT File (#66)		
NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. Editing of the file entries can be done using the "Edit blood products file [LRBLSEB]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu.		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.01 NAME free text, 2-40 characters	identifies product, i.e., blood/blood component	not applicable
.02 ABBREVIATION free text, 1-4 characters	characteristic/property; used to access this specific component and to identify the components on displays and/or reports	not applicable
.03 CAN BE MODIFIED set; yes/no	software control function, i.e., determines whether this product can be modified into other products	Required- use the [LRBLIDN] option
.04 IDENTIFIER set; BB/AB/T	software control function, i.e., determines whether this file entry can be accessed (only component/derivatives with IDENTIFIER = BB should be accessible at any prompt which references component)	no additional validation necessary once it has been demonstrated that file entries with an identifies of T or AB cannot be accessed.
.05 PRODUCT CODE free text, 1-5 characters	characteristic/property; used by bar code reader or by manual entry to access this specific component	Required - need to make sure that it is accurate & accesses the correct product
.055 DOD CODE free text, 2-5 characters	characteristic/property; free text used by the Department of Defense	Not Applicable for VA use
.06 MODIFICATION CRITERIA set; DIVIDED/POOLED/WASHED/ FROZEN/ LEUKOCYTE POOR/REJUVENATED/ DEGLYCEROLIZED/ IRRADIATED/ SEPARATED	software control function, i.e., determines the edit template used when this product is selected during modification of another product.	Required- use the [LRBLIDN] option

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.07 PATIENT/PRODUCT ABO set; MUST MATCH/ MUST BE COMPATIBLE	software control function, i.e., determines whether units selected for a patient must be identical or must be red cell compatible	no additional validation necessary once it has been demonstrated that other file entries function appropriately
.08 PATIENT/PRODUCT RH set; MUST MATCH/ MUST BE COMPATIBLE	software control function, i.e., determines whether units selected for a patient must be identical (MUST MATCH) or must be red cell compatible (MUST BE COMPATIBLE)	no additional validation necessary once it has been demonstrated that other file entries function appropriately
.09 PATIENT/PRODUCT REQUIREMENT set; CROSSMATCH/ PLASMA/ PATIENT COMPATIBILITY	software control function, i.e., determines whether units must be crossmatched or if the product contains large volumes of plasma which should be compatible with the patient's red cells	no additional validation necessary once it has been demonstrated that other file entries function appropriately
.1 VOLUME (ml) number, 0 decimals, 1-1000	characteristic/property;	Not Needed
.11 DAYS LEFT number, 2 decimals, .16-2557	software control function, i.e., calculates the new expiration date required if this product is prepared from another product present in inventory.	Required- use the [LRBLIDN] option
.12 ANTICOAGULANT/ ADDITIVE set; CPD/ACD/CPDA-1/ADSOL	software control function, i.e., prevents mixing of components during modifications (e.g., a product which has CPDA-1 cannot be modified to a product which has CPD as the anticoagulant)	no additional validation necessary once it has been demonstrated that other file entries function appropriately

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.13 COLLECTION/PREP HOURS number, 0 decimals, 1-144	software control function in the donor module options only, i.e., indicates the maximum time allowable between the DATE/TIME COLLECTION STARTED (65.54,4.2) and the DATE/TIME STORED (65.66,.03)	Required- use the [LRBLDC] option
.135 MAXIMUM STORAGE DAYS number, .16-3652 (4 hr to 10 years)	software control function in the donor module option, i.e., calculates the default shown for the EXPIRATION DATE (65.66,.04) software control function in the inventory module option, i.e., screens the entry for the EXPIRATION DATE/TIME (65,.06) for potential data entry errors	Required- use the [LRBLDC] option Required- use the [LRBLILR] option
.14 MODIFIED BEFORE RELEASE set; YES/NO	software control function, i.e., prevents issue/relocation of products which must be modified such as Frozen Red Blood Cells which must be deglycerolized before issue	Required- use the [LRBLIDR] option
.15 CAN BE REQUESTED set; YES/NO	software control function, i.e., prevents selection of products which should not be accessed/selected	no additional validation necessary once it has been demonstrated that other file entries function appropriately
.16 PATIENT SPECIMEN AGE ALLOWED number, 24-240 (1 to 10 days)	software control function, i.e., prevents selection of units of this product for specimens IF the difference between the current time and the BLOOD SAMPLE DATE/TIME (??) exceeds the entry in this field for this product	no additional validation necessary once it has been demonstrated that other file entries with the same time entry function appropriately

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.18 RETYPE AFTER PREPARATION set; YES/NO	software control function, i.e., determines whether units of this product must be retyped before issue/release. If YES, units which are created using the [LRBLIDN] option will appear on the Inventory testing worksheet generated by [LRBLIW].	no additional validation necessary once it has been demonstrated that other file entries functions appropriately
.19 CONTAINS RED BLOOD CELLS set; YES/NO	software control function, i.e., (1) determines whether units of this product must be retyped before issue/release. If YES, units will not be able to be released using [LRBLIDR] until required recheck results are entered. (2) used for sorting purposes on some reports	no additional validation necessary once it has been demonstrated that other file entries function appropriately
.21 MAX AGE FOR PEDIATRIC USE number, 0 decimals, 1-1827 (days)	software control function, i.e., determines whether units of this product can be modified into pediatric units	Required- use the [LRBLPED] option
.22 PEDIATRIC PRODUCT pointer to another entry in File 66	software control function, i.e., determines which products can be accessed when modifying a unit in inventory using the [LRBLPED] option; however, both must also have the same entry in the ANTICOAGULANT/ ADDITIVE field	Required- use the [LRBLPED] option
.23 SPECIFIC GRAVITY set; 1.06/1.08/1.03	algorithm function in the inventory module [LRBLPED] option, i.e., used to convert the volume of the unit in mls. into an equivalent wt. in gms.	no additional validation necessary once it has been demonstrated that other comparable file entries function appropriately

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.24 MAXIMUM INFUSION TIME(MIN) number, 0 decimals, 1-999 (minutes)	algorithm function used to determine which units should be included in the Prolonged transfusion times report generated by the [LRBLPIT] option	no additional validation necessary once it has been demonstrated that other comparable file entries function appropriately
.25 AUTOLOGOUS/ DIRECTED COMPONENT set;AUTOLOGOUS/ DIRECTED/NEITHER	software control function, i.e., determines whether additional data is needed to restrict selection of the unit for the intended patient (RESTRICTED FOR field)	no additional validation necessary once it has been demonstrated that other comparable file entries function appropriately
.26 ADMINISTRATIVE CATEGORY set; WHOLE BLOOD/ RBC/FROZEN RBC/DEGLYC RBC/LEUCODEPLETED RBC/WASHED RBC/FFP	algorithm function used to determine which units should be included in several different reports, e.g. Phenotyped units available [LRBLIPH] and Blood Bank Administrative Data [LRBLA]	no additional validation necessary once it has been demonstrated that other comparable file entries function appropriately
.27 POOLED PRODUCT set; YES/NO	algorithm function used by the integrity check routine in the [LRBLII] option to determine which fields may have missing data software control function, i.e., determines whether a unit of that specific product can be accessed thorough the Edit pooled blood product [LRBLJM] option	no additional validation necessary once it has been demonstrated that other comparable file entries function appropriately Required-use the [LRBLJM] option
.28 ASK BAG LOT # set; YES/NO	software control function, i.e., determines whether the BAG LOT # field (65,1.1) should be included in the edit template used by the [LRBLIDN] option when modifying units	Required-use the [LRBLIDN] option

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
1 DESCRIPTION (Subfile 66.09) .01 DESCRIPTION word processing; 1-50 characters	characteristic/property; intended for use for display purposes in future	Not applicable
2 SYNONYM (Subfile 66.021) .01 SYNONYM free text; 2-50 characters	characteristic/property; used for look-up access purposes only	Required - need to make sure that it is accurate
3 MODIFY TO (Subfile 66.03) .01 MODIFY TO pointer to File 66	software control function, i.e., determines which products can be accessed when modifying a unit in inventory using the [LRBLIDN] option	Required- use the [LRBLIDN] option
3 MODIFY TO (Subfile 66.03) .02 NOT ONLY ONE ALLOWED set;YES/NO	software control function, i.e., determines whether more than one product may be created when modifying a unit in inventory using the [LRBLIDN] option	Required- use the [LRBLIDN] option
4 SUPPLIER (Subfile 66.01) .01 SUPPLIER free text; 1-30 characters	software control, i.e. determines characteristics based on subfields detailed below	Required - need to make sure that it is accurate- use the [LRBLILR] option

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
4 SUPPLIER (Subfile 66.01) .03 ADDRESS LINE 1 free text; 1-30 characters .04 ADDRESS LINE 2 free text; 1-30 characters .05 ADDRESS LINE 3 free text; 1-30 characters .06 CITY free text; 1-30 characters .07 STATE pointer to State File (#5) .08 ZIP CODE free text; 5-9 characters .09 PHONE free text; 4-30 characters	characteristic/property; used for look-up and information purposes only	Required - need to make sure that it is accurate
4 SUPPLIER (Subfile 66.01) .02 COST number, 0-9999	characteristic/property; used for calculating expenses on various transaction reports	Required - need to make sure that it is accurate- use the [LRBLRIT] option
4 SUPPLIER (Subfile 66.01) .1 SUPPLIER PREFIX NUMBER free text, 1-3 characters	software control function, i.e., determines the prefix to be added to the unit ID which is scanned by the bar code reader when entering a unit in inventory using the [LRBLILR] option	Required - need to make sure that it is accurate- use the [LRBLILR] option
4 SUPPLIER (Subfile 66.01) .11 REGISTRATION NUMBER free text, 7-9 digits	characteristic/property; used for reference/information only	Not applicable

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
4 SUPPLIER (Subfile 66.01) .12 UNIT LABEL NON-STANDARD set; YES/NO	software control function, i.e., controls the translation of the unit ID which is scanned by the bar code reader when entering a unit in inventory using the [LRBLILR] option NOTE: Standard=alphanumeric (NO) Non-Standard=numeric (YES)	Required - need to make sure that it is accurate- use the [LRBLILR] option
1 LOT # (Subfile 66.02) .01 LOT # free text, 1-30 characters .02 EXPIRATION DATE date	not currently used by the software	Not applicable
5 CRITERIA FOR USE (Subfile 66.05) .01 CRITERIA FOR USE word processing	characteristic/property; intended for use for display purposes in future	Not applicable
6 TESTS TO CHECK (Subfile 66.08) .01 TESTS TO CHECK pointer to Laboratory Test File (#60) .02 SPECIMEN pointer to Topography Field File (#61) .03 > OR < TEST VALUE free text	algorithm function used to identify/flag non pre-op component requests which exceed the audit criteria entered which evaluates the most recent data in File 63 for the tests identified	Required-use either the [LRBLPCS] option or the [LRBLPLOGIN] option
7 REQUISITION INSTRUCTIONS (Subfile 66.07) .01 REQUISITION INSTRUCTIONS word processing	characteristic/property; intended for use for display purposes in future	Not applicable

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
8 PRE-OP TESTS TO CHECK (Subfile 66.08) .01 PRE-OP TESTS TO CHECK pointer to Laboratory Test File (#60) .02 SPECIMEN pointer to Topography Field File (#61) .03 > OR < TEST VALUE free text	algorithm function used to identify/flag pre-op component requests which exceed the audit criteria entered which evaluates the most recent data in File 63 for the tests identified	Required-use either the [LRBLPCS] option or the [LRBLPLOGIN] option
10 ASSOCIATED DIVISION (Subfile 66.1) .01 ASSOCIATED DIVISION pointer to INSTITUTION File (#4)	software control which limits access to products based on a comparison of the division of the user at a given point in time with the products attempting to be requested.	no additional validation necessary once it has been demonstrated that other comparable file entries function appropriately
500 WKLD CODE (Subfile 66.06) .01 WKLD CODE pointer to WKLD CODE File (#64)	characteristic/property used for workload capture by the [LRBLIDN] option and the [LRBLDCP] option	no additional validation necessary once it has been demonstrated that other comparable file entries function appropriately

Request for File Changes to the FUNCTION FIELD file (#61.3)

TYPE OF REQUEST:

❒ Additional blood group antigen/antibody
❒ Change in blood group antigen/antibody entry
(Specify: _____)

REASON FOR REQUEST:

❒ DHCP Software Patch (Patch #: _____)
❒ Change in standard operating procedure
❒ Change in scope of services provided
❒ Other (Specify: _____)

NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. Editing of the file entries can be done using the "Edit Corresponding Antigen/Antibody [LRBLSNO]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu. Use of this option will restrict file access to the fields shown below.

Consult the table on Validation Requirements for File Changes to the FUNCTION FIELD file (#61.3) which includes the columns labelled "purpose of the field" and "changes require validation?" for the rationale and details regarding the functionality of the field and whether additions/changes require software validation.

Additions/Change to the FUNCTION FIELD File (#61.3)

Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.01 NAME identifies antigen/antibody		(free text, 1-30 characters)	
.04 CORRESPONDING ANTIGEN/ANTIBODY compares entries in the ANTIBODIES IDENTIFIED field (#63,.075) for a specific patient with entries in the RBC ANTIGEN S ABSENT field (#65,70) for the unit.		(pointer to File 61.3)	Accept. Unaccept.
.06 COMPATIBILITY FACTOR used to calculate the percentage of compatible units for inclusion on the Blood Bank Consultation Report generated for patients with clinically significant antibodies		(number, 3 decimals, 0-1)	Accept. Unaccept.

Additions/Change to the FUNCTION FIELD File (#61.3) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Valida-tion**
5 JOURNAL REFERENCE (Subfile 61.32) .01 TITLE OF ARTICLE 1 AUTHOR 2 MEDICAL JOURNAL 3 VOLUME 4 STARTING PAGE 5 DATE characteristics/properties which print on the Blood Bank Consultation Report generated for patients with clinically significant antibodies if field 61.32,6 is set to YES		.01 TITLE OF ARTICLE free text, 1-80 characters 1 AUTHOR free text, 1-80 characters 2 MEDICAL JOURNAL pointer to LAB JOURNAL file (#95) 3 VOLUME free text, 1-6 characters 4 STARTING PAGE free text, 1-6 characters 5 DATE date	Accept. Unaccept.
5 JOURNAL REFERENCE (Subfile 61.32) continued 6 LIST ON PATIENT RECORD determines which journal references to include on the Blood Bank Consultation Report generated for patients with clinically significant antibodies		(set) YES NO	Accept. Unaccept.
7 COMMENT prints on the Blood Bank Consultation Report generated for patients with clinically significant antibodies		(free text)	Accept. Unaccept.

Change Control Summary for Additions/Changes to the FUNCTION FIELD file (#61.3)

Training

❒ None needed ❒ Completed/documented (Date _____ by _____)

Comments: _____

Documentation

❒ New printout of file obtained

❒ No procedure change needed ❒ Procedure change completed (Date _____)

Name of procedure: _____

Validation Risk Assessment and Testing Summary:
*see separate attached documentation for test cases

Date Tested _____ Tested by: _____

❒ None needed ❒ Acceptable* ❒ Unacceptable*

Comments: _____

Supervisory Review:

Signature: _____ (BB Supervisor)

Signature: _____ (BB Medical Director)

Signature: _____ (LIM/IRM Staff)

Date Implemented in Production: _____

Validation Requirements for File Changes to FUNCTION FIELD file (#61.3)

FUNCTION FIELD File (#61.3)		
NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. Editing of the file entries can be done using the "Edit Corresponding Antigen/Antibody [LRBLSNO]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu. Use of this option will restrict file access to the fields shown below.		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.01 NAME free text, 1-30 characters	identifies antigen/antibody	
.04 CORRESPONDING ANTIGEN/ANTIBODY pointer to File 61.3	software control, i.e., compares entries in the ANTIBODIES IDENTIFIED field (#63,.075) for a specific patient with entries in the RBC ANTIGENS ABSENT field (#65,70) for the unit. For example, since anti-K is a clinically significant antibody, if you selected "51810 ANTI K", you would expect to find an entry of "50500 K" in the CORRESPONDING ANTIGEN/ANTIBODY field.	Required - use the [LRBLPX] and the [LRBLIDR] options
.06 COMPATIBILITY FACTOR number, 3 decimals, 0-1	characteristic/property which is used to calculate the percentage of compatible units for inclusion on the Blood Bank Consultation Report generated for patients with clinically significant antibodies	Required - use the [LRUCN] option

FUNCTION FIELD File (#61.3) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
5 JOURNAL REFERENCE (Subfile 61.32) .01 TITLE OF ARTICLE free text, 1-80 characters 1 AUTHOR free text, 1-80 characters 2 MEDICAL JOURNAL pointer to LAB JOURNAL file (#95) 3 VOLUME free text, 1-6 characters 4 STARTING PAGE free text, 1-6 characters 5 DATE date	characteristics/properties which print on the Blood Bank Consultation Report generated for patients with clinically significant antibodies if field 61.32,6 is set to YES	Required- check for accuracy - use the [LRUCN] option
5 JOURNAL REFERENCE (Subfile 61.32) 6 LIST ON PATIENT RECORD set; YES/NO	software control, i.e., determines which journal references to include on the Blood Bank Consultation Report generated for patients with clinically significant antibodies if field 61.32,6 is set to YES	Required - use the [LRUCN] option
7 COMMENT	characteristic/property which prints on the Blood Bank Consultation Report generated for patients with clinically significant antibodies	Required - use the [LRUCN] option

Request for File Changes to BLOOD BANK UTILITY file (#65.4)

This file serves two purposes, one in the donor module and the other in providing choices for types of transfusion reactions.

TYPE OF REQUEST:
- ❒ Additional entry (e.g. donor group/transfusi on reaction)
- ❒ Change in entry
  (Specify: _____)

REASON FOR REQUEST:
- ❒ DHCP Software Patch (Patch #: _____)
- ❒ Change in standard operating procedure
- ❒ Change in scope of services provided
- ❒ Other (Specify: _____)

NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. Editing of the file entries can be done using the "Edit blood bank utility [LRBLSEU]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu.

Consult the table on pages E-53 through E-54 which includes the columns labeled "purpose of the field" and "changes require validation?" for the rationale and details regarding the functionality of the field and whether additions/changes require software validation.

Additions/Change to the BLOOD BANK UTILITY File (#65.4)

Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Valida-tion**
.01 NAME identifies entry, i.e., name of the collection site, donor group affiliation, code related to the donor history or type of transfusion reaction		(free text, 1-30 characters)	Not applic.
.02 SCREEN determines which entries in the file are accessible during specific data entry options		(set) GROUP AFFILIATION DEFERRAL CODE COLLECTION SITE GR0UP AFFILIATION& COLLECTION SITE DONOR REACTION TRANSFUSION REACTION	Not needed Accept. Unaccept .

**not used for entries for which the SCREEN =DONOR REACTION or TRANSFUSION REACTION

Additions/Change to the BLOOD BANK UTILITY File (#65.4) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.03 FULL NAME characteristic/property		(free text, 1-80 charac.)	Not Applic.
1.1 ADDRESS LINE 1 characteristic/property **		(free text, 1-30 charac.)	Not Applic.
1.2 ADDRESS LINE 2 characteristic/property **		(free text, 1-30 charac.)	Not Applic.
1.3 ADDRESS LINE 3 characteristic/property **		(free text, 1-30 charac.)	Not Applic.
1.4 CITY characteristic/property**		(free text, 1-30 charac.)	Not Applic.
1.5 STATE characteristic/property **		(pointer to State File(#5))	Not Applic.
1.6 ZIP CODE characteristic/property**		(free text, 5-9 charac.)	Not Applic.
1.7 PHONE 1 characteristic/property**		(free text, 3-15 charac.)	Not Applic.
1.8 PHONE 2 characteristic/property**		(free text, 3-15 charac.)	Not Applic.
1.9 GROUP LEADER characteristic/property**		(free text, 3-30 charac.)	Not Applic.

Change Control Summary for Additions/Changes to the BLOOD BANK UTILITY file (#65.4)

Training

❒ None needed ❒ Completed/documented (Date _____ by _____)

Comments: _____

Documentation

❒ New printout of file obtained

❒ No procedure change needed ❒ Procedure change completed (Date _____)

Name of procedure: _____

Validation Risk Assessment and Testing Summary:
*see separate attached documentation for test cases

Date Tested _____ Tested by: _____

❒ None needed ❒ Acceptable* ❒ Unacceptable*

Comments: _____

Supervisory Review:

Signature: _____ (BB Supervisor)

Signature: _____ (BB Medical Director)

Signature: _____ (LIM/IRM Staff)

Date Implemented in Production: _____

Request for File Changes to the BLOOD BANK UTILITY file (#65.4)- DONOR HISTORY QUESTIONS

TYPE OF REQUEST:

- ❒ Additional donor question
- ❒ Change in existing donor history question (Specify: _____)

REASON FOR REQUEST:

- ❒ Change in accrediting/regulatory requirement
- ❒ Change in standard operating procedure
- ❒ Change in scope of services provided
- ❒ Other (Specify: _____)

NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. If editing is limited to changes in field 2 DONOR HISTORY, use the "Edit donor history questions [LRBLSEH] option in the "Blood donor edit options..[LRBLSD]" submenu of the "Supervisor [LRBLS]" menu.

Consult the table Validation Requirements for File Changes to the BLOOD BANK UTILITY FILE (#65.4) which includes the columns labeled "purpose of the field" and "changes require validation?" for the rationale and details regarding the functionality of the field and whether additions/changes require software validation.

Additions/Change to the DONOR HISTORY QUESTIONS in the BLOOD BANK UTILITY File (#65.4) Field 2 DONOR HISTORY (word processing)		
Current Entry* *if applicable	**New Entry** (word processing)	**Validation**
		Accept. Unaccept.
		Accept. Unaccept.
		Accept. Unaccept.
		Accept. Unaccept.

Change Control Summary for Additions/Changes to the DONOR HISTORY QUESTIONS in the BLOOD BANK UTILITY file (#65.4) Field 2 DONOR HISTORY (word processing)

Training

❒ None needed ❒ Completed/documented (Date _____ by _____)

Comments: _____

Documentation

❒ New printout of file obtained

❒ No procedure change needed ❒ Procedure change completed (Date _____)

Name of procedure: _____

Validation Risk Assessment and Testing Summary:
*see separate attached documentation for test cases

Date Tested _____ Tested by: _____

❒ None needed ❒ Acceptable* ❒ Unacceptable*

Comments: _____

Supervisory Review:

Signature: _____ (BB Supervisor)

Signature: _____ (BB Medical Director)

Signature: _____ (LIM/IRM Staff)

Date Implemented in Production: _____

Request for File Changes to the BLOOD BANK UTILITY file (#65.4)- DONOR CONSENT

TYPE OF REQUEST:

❒ Change in wording of donor consent
(Specify: _____)

REASON FOR REQUEST:

❒ Change in accrediting/regulatory requirement
❒ Change in standard operating procedure
❒ Change in scope of services provided
❒ Other (Specify: _____)

NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. If editing is limited to changes in field 3 COMMENT, use the "Edit donor consent[LRBLDCX] option in the "Blood donor edit options..[LRBLSD]" submenu of the "Supervisor [LRBLS]" menu.

Consult the table Validation Requirements for File Changes to the BLOOD BANK UTILITY FILE (#65.4) which includes the columns labelled "purpose of the field" and "changes require validation?" for the rationale and details regarding the functionality of the field and whether additions/changes require software validation.

Additions/Change to the DONOR HISTORY QUESTIONS in the BLOOD BANK UTILITY File (#65.4) Field 3 COMMENT (word processing)		
Current Entry* *if applicable	**New Entry** (word processing)	**Validation**
		Accept. Unaccept.

Change Control Summary for Additions/Changes to the DONOR CONSENT in the BLOOD BANK UTILITY file (#65.4) Field 3 COMMENT (word processing)

Training

❒ None needed ❒ Completed/documented (Date _____ by _____)

Comments: _____

Documentation

❒ New printout of file obtained

❒ No procedure change needed ❒ Procedure change completed (Date _____)

Name of procedure: _____

Validation Risk Assessment and Testing Summary:
*see separate attached documentation for test cases

Date Tested _____ Tested by: _____

❒ None needed ❒ Acceptable* ❒ Unacceptable*

Comments: _____

Supervisory Review:

Signature: _____ (BB Supervisor)

Signature: _____ (BB Medical Director)

Signature: _____ (LIM/IRM Staff)

Date Implemented in Production: _____

Validation Requirements for File Changes to the BLOOD BANK UTILITY file (#65.4)

BLOOD BANK UTILITY File (#65.4)

NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. Editing of the file entries can be done using the "Edit blood bank utility [LRBLSEU]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu.

This file serves two purposes, one in the donor module and the other in providing choices for types of transfusion reactions.

If editing is limited to changes in field 2 DONOR HISTORY, use the "Edit donor history questions [LRBLSEH] option in the "Blood donor edit options..[LRBLSD]" submenu of the "Supervisor [LRBLS]" menu.

If editing is limited to changes in field 3 COMMENT, use the "Edit donor consent[LRBLDCX] option in the "Blood donor edit options..[LRBLSD]" submenu of the "Supervisor [LRBLS]" menu.

Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.01 NAME free text, 2-30 characters	identifies entry, e.g. the name of the collection site, donor group affiliation, coded item related to the donor history or type of transfusion reaction	
.02 SCREEN set; GROUP AFFILIATION/ DEFERRAL CODE/ COLLECTION SITE/ GROUP AFFILIATION & COLLECTION SITE/ DONOR REACTION/ TRANSFUSION REACTION	software control, i.e. determines which entries in the file are accessible during data entry options	yes only if the specific screen has not been validated previously no additional validation necessary once it has been demonstrated that other comparable file entries function appropriately
.03 FULL NAME free text, 1-80 characters	characteristic/property	yes - need to make sure that it is accurate & accesses the correct file entry
1.1 ADDRESS LINE 1 free text, 1-30 characters	characteristic/property	not applicable
1.2 ADDRESS LINE 2 free text, 1-30 characters	characteristic/property	not applicable

BLOOD BANK UTILITY File (#65.4) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
1.3 ADDRESS LINE 3 free text, 1-30 characters	characteristic/property	not applicable
1.4 CITY free text, 1-30 characters	characteristic/property	not applicable
1.5 STATE pointer to State File (#5)	characteristic/property	not applicable
1.6 ZIP CODE free text, 5-9 characters	characteristic/property	not applicable
1.7 PHONE 1 free text, 3-15 characters	characteristic/property	not applicable
1.8 PHONE 2 free text, 3-15 characters	characteristic/property	not applicable
1.9 GROUP LEADER free text, 3-30 characters	characteristic/property	not applicable
2 DONOR HISTORY word processing	software control, i.e. entries on the donor history questionaire	yes- use the [LRBLDR] option
3 COMMENT word processing	software control, i.e. entries on the donor consent paragraph	yes- use the [LRBLDR] option

Request for File Changes to the LABORATORY SITE file (#69.9

TYPE OF REQUEST:
- ❒ Additional entry
- ❒ Change in entry
  (Specify: _____)

REASON FOR REQUEST:
- ❒ DHCP Software Patch (Patch #: _____)
- ❒ Change in standard operating procedure
- ❒ Change in scope of services provided
- ❒ Other (Specify: _____)

NOTE: Only 1 entry exists in this file, i.e. HOSPITAL. Additions to the file cannot be made. Editing of the file entry should be done using the "Edit blood bank site parameters [LRBLSSP]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu. This option restricts access to only specific fields applicable to the Blood Bank software.

Consult the table on Validation Requirements for File Changes to the LABORATORY SITE FILE (#69.9) which includes the columns labelled "purpose of the field" and "changes require validation?" for the rationale and details regarding the functionality of the field and whether additions/changes require software validation.

**potential future use; not currently in use by the software

Additions/Change to the LABORATORY SITE FILE (#69.9)			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.18 BLOOD DONOR UNIT ID PREFIX characteristic which identifies the number of eye readable (non bar coded) characters which appear as a prefix for the facility's blood donor unit ID number allowing the cross references to be set appropriately		(number, 1-3 characters)	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .01 BLOOD BANK OPTION (multiple)		1 DONOR 2 INVENTORY** 3 PATIENT 4 INQUIRIES** 5 REPORTS** 6 SUPERVISOR** 7 TEST WORKLISTS** 8 WARD**	Not Applic.-see specifics below

Additions/Change to the LABORATORY SITE FILE (#69.9) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
8 BLOOD BANK DEFAULTS (Subfile 69.98) .02 FIRST DEFAULT For DONOR: determines whether ABO/Rh test results should be moved from the Donor File (#65.5) to the Inventory File (#65)		(set) YES NO	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .02 FIRST DEFAULT For PATIENT: determines whether prompts for direct antiglobulin testing should be included in the LRBLSCREEN edit template used in the [LRBLPET] option to enter test results		(set) YES NO	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .03 SECOND DEFAULT For DONOR: determines whether the military rank should be asked-used only by the Department of Defense		(set) YES NO	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .04 THIRD DEFAULT For DONOR: determines whether the bag lot # should be included in the [LRBLDC] option		(set) YES NO	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .05 FOURTH DEFAULT For DONOR: determines whether the donor's social security number should be included in the [LRBLDR] option		(set) YES NO	Accept. Unaccept.

Additions/Change to the LABORATORY SITE FILE (#69.9) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
8 BLOOD BANK DEFAULTS (Subfile 69.98) .06 FIFTH DEFAULT For DONOR: determines whether ALT testing is to be included in the transfusion transmitted disease testing performed on blood donors		(set) YES NO	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .07 SIXTH DEFAULT For DONOR: determines whether HIV Antigen testing is to be included in the transfusion transmitted disease testing performed on blood donors		(set) YES NO	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .1 MAJOR SECTION characteristic/property, i.e., accession area to be used for workload recording purposes		(pointer to Accession File (#68)	Not Applic.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .11 SUBSECTION characteristic/property, i.e., accession area to be used for workload recording purposes		(pointer to Accession File (#68)	Not Applic.
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .01 BLOOD BANK INSTITUTION characteristic/property, i.e., institution to be considered primary for this site		(pointer to Institution File (#4)	Not Applic.

Additions/Change to the LABORATORY SITE FILE (#69.9) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .02 INVENTORY MAJOR SECTION characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Inventory File (#65)		(pointer to Accession File (#68)	Not Applic.
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .02 INVENTORY SUBSECTION characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Inventory File (#65)		(pointer to Accession File (#68)	Not Applic.
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .04 DONOR MAJOR SECTION characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Blood Donor File (#65.5)		(pointer to Accession File (#68)	Not Applic.
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .05 DONOR SUBSECTION characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Blood Donor File (#65.5)		(pointer to Accession File (#68)	Not Applic.

Additions/Change to the LABORATORY SITE FILE (#69.9) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .06 MULTIPLE ACCESSION AREA determines whether the site is multidivisional and/or has more than one accession area for Blood Bank NOTE: This field cannot be accessed through the [LRBLSSP] option. It must be edited by someone with a higher security level for access. to FileManager.		(set) YES NO	Accept. Unaccept.

Change Control Summary for Additions/Changes to the LABORATORY SITE file (#69.9)

Training

❒ None needed ❒ Completed/documented (Date _____ by _____)

Comments: _____

Documentation

❒ New printout of file obtained

❒ No procedure change needed ❒ Procedure change completed (Date _____)

Name of procedure: _____

Validation Risk Assessment and Testing Summary:
*see separate attached documentation for test cases

Date Tested _____ Tested by: _____

❒ None needed ❒ Acceptable* ❒ Unacceptable*

Comments: _____

Supervisory Review:

Signature: _____ (BB Supervisor)

Signature: _____ (BB Medical Director)

Signature: _____ (LIM/IRM Staff)

Date Implemented in Production: _____

Validation Requirements for File Changes to the LABORATORY SITE file (#69.9)

LABORATORY SITE File (#69.9)

NOTE: Only one entry exists in this file, i.e. HOSPITAL. Additions to the file cannot be made. Editing of the file entry should be done using the "Edit blood bank site parameters [LRBLSSP]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu.

This file allows the site to customize some functionality. In the case of Blood Bank, this feature is used primarily for determining the content of specific edit templates for which there is some variability in the data which an individual facility might which to enter.

Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.18 BLOOD DONOR UNIT ID PREFIX number, 1-3 characters	software control, i.e. identifies the number of eye readable (non bar coded) characters which appear as a prefix for the facility's blood donor unit ID number to allow creation of an appropriate cross reference for the bar coded portion	Required- use the [LRBLDCP] option to scan the unit ID number to access the unit, and then by manual entry of the entire unit ID
8 BLOOD BANK DEFAULTS (Subfile 69.98) .01 BLOOD BANK OPTION (multiple) 1 DONOR 2 INVENTORY** 3 PATIENT 4 INQUIRIES** 5 REPORTS** 6 SUPERVISOR** 7 TEST WORKLISTS** 8 WARD**	software control functions as detailed in the subfields below ** indicates placeholders for future functionality (not currently in use)	Not Applicable- see specific subfields below
8 BLOOD BANK DEFAULTS (Subfile 69.98) .02 FIRST DEFAULT (set:YES/NO)	software control, i.e. for DONOR: determines whether ABO/Rh test results should be moved from the Donor File (#65.5) to the Inventory File (#65). This requires the donor rechecks to be done and entered via the [LRBLDUC] option before the unit is released. If the results are not moved, the unit rechecks must be done before the unit can be released on a patient.	Required- use the [LRBLDRR] option to release the unit and the [LRBLISPD] option to see whether the ABO and Rh were transferred

LABORATORY SITE File (#69.9) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
8 BLOOD BANK DEFAULTS (Subfile 69.98) .02 FIRST DEFAULT (set:YES/NO)	software control, i.e., for PATIENT: determines whether prompts for direct antiglobulin testing should be included in the LRBLSCREEN edit template used in the [LRBLPET] option to enter test results	Yes
8 BLOOD BANK DEFAULTS (Subfile 69.98) .03 SECOND DEFAULT (set:YES/NO)	software control, i.e., for DONOR: determines whether the military rank should be asked- NOTE: used only by the Department of Defense	Yes
8 BLOOD BANK DEFAULTS (Subfile 69.98) .04 THIRD DEFAULT (set:YES/NO)	software control, i.e., for DONOR: determines whether the bag lot # should be included in the [LRBLDC] option	Yes
8 BLOOD BANK DEFAULTS (Subfile 69.98) .05 FOURTH DEFAULT (set:YES/NO)	software control, i.e., for DONOR: determines whether the donor's social security number should be included in the [LRBLDR] and the [LRBLDD] options	Yes
8 BLOOD BANK DEFAULTS (Subfile 69.98) .06 FIFTH DEFAULT (set:YES/NO)	software control, i.e., for DONOR: determines whether ALT testing is to be included in the transfusion transmitted disease testing performed on blood donors	Yes
8 BLOOD BANK DEFAULTS (Subfile 69.98) .07 SIXTH DEFAULT (set:YES/NO)	software control, i.e., for DONOR: determines whether HIV Antigen testing is to be included in the transfusion transmitted disease testing performed on blood donors	Yes
8 BLOOD BANK DEFAULTS (Subfile 69.98) .1 MAJOR SECTION pointer to Accession File (#68)	characteristic/property, i.e., accession area to be used for workload recording purposes	Not needed- used for workload recording purposes

LABORATORY SITE File (#69.9) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
8 BLOOD BANK DEFAULTS (Subfile 69.98) .11 SUBSECTION pointer to Accession File (#68)	characteristic/property, i.e., accession area to be used for workload recording purposes	Not needed- used for workload recording purposes
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .01 BLOOD BANK INSTITUTION (pointer to Institution File (#4)	characteristic/property, i.e., institution to be considered primary for this site	Not needed- used for workload recording purposes
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .02 INVENTORY MAJOR SECTION pointer to Accession File (#68)	characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Inventory File (#65)	Not needed- used for workload recording purposes
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .02 INVENTORY SUBSECTION pointer to Accession File (#68)	characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Inventory File (#65)	Not needed- used for workload recording purposes
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .04 DONOR MAJOR SECTION pointer to Accession File (#68)	characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Blood Donor File (#65.5)	Not needed- used for workload recording purposes
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .05 DONOR SUBSECTION pointer to Accession File (#68)	characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Blood Donor File (#65.5)	Not needed- used for workload recording purposes

LABORATORY SITE File (#69.9) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .06 MULTIPLE ACCESSION AREA set; YES/ NO	software control function, i.e. determines whether the site is multidivisional and/or has more than one accession area for Blood Bank NOTE: This field cannot be accessed through the [LRBLSSP] option. It must be edited by someone with a higher security level for access. to FileManager.	Yes- see the listing of control functions and the Test Case Tracking sheets. Editing of this parameter would entail significant validation of multidivisional functionality.